LOS ANGELES COUNTY DEPARTMENT OF PUBLIC HEALTH
POLICY REGARDING RESEARCH AND RELATED ACTIVITIES INVOLVING HUMAN SUBJECTS

PURPOSE

The purpose is to establish policy for the Los Angeles County Department of Public Health (DPH) Institutional Review Board (IRB) to review all human subjects research and related activities that are sponsored by, or involve, the Department.

DEFINITIONS

A "human subject" is a living individual from whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

"Research" is (1) a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or (2) a systematic collection or analysis of data with the intent to generate new knowledge.

"Related activities" means any process that involves collecting data from or about individuals other than that related to provision of clinical care or conducting statutorily mandated surveillance and disease or environmental investigation.

ETHICAL PRINCIPLES

The Los Angeles County Department of Public Health (DPH) is guided by the ethical principles for research involving human subjects stated in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the Belmont Report). DPH specifically recognizes the Belmont Report's principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice and applies these principles in all research covered by these policies and procedures.

In addition, all DPH-funded or conducted research must meet the requirements stated in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) often referred to as the "Common Rule." [See Appendix B] Any research involving products regulated by the U. S. Food and Drug Administration (FDA) must meet the requirements of 45 CFR 46 *and* FDA regulations for protecting human subjects, 21 CFR 50 and 56.

POLICY

DPH acknowledges and accepts its responsibility for protecting the rights and welfare of human research subjects and all individuals from or about whom it collects individual-level data.

DPH acknowledges that it and especially its investigators bear full responsibility for performing all research covered by this policy, including complying with federal, state, and local laws as they apply to such research.

The boundary between "research" and other activities that may be considered "practice" or otherwise not research, e.g. systematic program evaluation, quality improvement and needs assessment, is often hard to delineate; the methods and intent are overlapping. DPH acknowledges its responsibility for protecting the rights and welfare of all individuals with whom we interact and from or about whom collect data whether in a formal research project. Furthermore the federal Common Rule and the oversight Office of Human Research Subjects Protections (OHRP) explicitly grant authority to institutions such as DPH to expand protections and procedures beyond the minimum required by law. Therefore, DPH explicitly considers these ethical principles and these review and oversight procedures to apply to all activities in which individual-level data are collected, with the exception of the collection of data in the course of providing clinical care or conducting statutorily mandated surveillance and disease outbreak or environmental investigations. The DPH IRB may simplify or otherwise modify the specific manner of complying with the following requirements for projects classified as "non-research," but the principles must be embodied in an appropriate form in all projects and all projects are subject to IRB review and oversight.

DPH assures that it and its investigators will satisfy the following requirements before involving human subjects:

1. Risks to participants are minimized:
(a) By using procedures that are consistent with sound research design but do not unnecessarily expose participants to risks, and
(b) Whenever appropriate, researchers do not duplicate procedures that are already being performed on participants for prevention, diagnostic, or treatment purposes.

2. Risks to participants are reasonable compared to the knowledge that might reasonably be expected to result.

3. Participant selection is equitable.

4. The principal investigator will acquire informed consent appropriate to the project from each prospective participant or the participant's legally authorized representative, unless otherwise exempted by state or federal law.

5. When required, the principal investigator will appropriately document informed consent and will retain it in a secure manner such as a locked file cabinet or protected computer server.

6. The research plan ensures participant safety.

7. Each research project will have adequate provisions to protect individual participant's privacy and maintain data confidentiality.

8. DPH recognizes that for those who are likely to be vulnerable to coercion, undue influence or heightened risks, such as children, prisoners, pregnant women, mentally disabled persons, or

economically or educationally disadvantaged persons, the research plan needs appropriate additional safeguards.

9. DPH encourages and promotes constructive communication among its administrators, research supervisors, research investigators, and all other relevant parties to maintain a high level of awareness for safeguarding research subjects' rights and welfare.

10. DPH oversees projects by reviewing each open project at least annually to assure that investigators are effectively applying its practices and procedures designed for the protection of the rights and welfare of human subjects.

11. DPH posts this statement of ethical principles and policy on its Web page as a separate document.

12. DPH requires that principal investigators and other key project staff be trained in the rights and welfare of human subjects.

13. DPH additionally requires that each project approved by the IRB: a) addresses an important public health or health services problem; b) employs an appropriate methodology and analysis plan capable of yielding valid information about the problem; c) describes means by which the resulting data will be utilized and/or shared with community and other stakeholders; d) includes appropriate community consultation and engagement; e) includes provisions for being conducted in or translated/interpreted into whatever languages are primarily spoken by a significant proportion of the source or target population.

RESPONSIBILITIES

The director of each bureau, division, program or office in DPH is responsible to ensure that the Chair of the DPH IRB is consulted on any project or activity in his or her jurisdiction that may involve human subjects research or related data-collection activities not explicitly exempt by law, i.e. clinical care and statutorily mandated surveillance or investigation.

Unless the Chair of the IRB determines that a proposed project or activity is legally exempt from review, the proposal will be submitted for the appropriate level of review by the DPH IRB. The IRB must approve or exempt the proposed project or activity before it can begin.

The director of each bureau, division, program or office in DPH shall ensure that all IRB requirements are fulfilled, including prompt reporting of modifications to approved protocols, complaints, and adverse events. He or she shall ensure that approved projects are submitted for re-approval prior to the approval expiration date, if the project will continue past this date, and that the IRB is notified when all activities have been completed, including analyses and preparation of manuscripts or reports, and a final report submitted.